PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H 2131 PCT S3	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/06930	International filing date *(day/month/year)* 30.06.2003	Priority date *(day/month/year)* 08.07.2002
International Patent Classification (IPC) or both national classification and IPC C07K14/47		
Applicant BOUGUELERET, Lydie, et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1/2-2/2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09.02.2004	02.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Sirim, P Telephone No. +49 89 2399-7732

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/06930

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-82 as originally filed

Claims, Numbers

1-13 received on 09.02.2004 with letter of 09.02.2004

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☒ furnished subsequently to this Authority in written form.

   ☒ furnished subsequently to this Authority in computer readable form.

   ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 9-13

   because:

   ☒ the said international application, or the said claims Nos. 9-13 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-13
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-13
Industrial applicability (IA)	Yes:	Claims	1-8
	No:	Claims	9-13

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. **Subject-matter under Art. 34(4)(a) and Rule 67(1) PCT**

   The subject-matter of claims 9 to 13 relates to methods for treatment practised on the human or animal body and thus relates to subject-matter defined by Art. 34(4)(a) and Rule 67(1) PCT. Therefore, these claims have been only partially searched and the search has been limited on the alleged effects of the compound/composition.

   For the assessment of said claims on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States.

   The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V

Reasoned statement under Art. 35(2) PCT with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. **Documents**

   The following documents have been taken into consideration,

   D1: WO 02 13857 A (EGYED ALENA; FRITZ JOERG (AT); MATTNER FRANK (AT); BUSCHLE MICHAEL) 21 February 2002 (2002-02-21)

   D2: WO 02 09738 A (MCANULTY JONATHAN F; REID TED W (US); MURPHY CHRISTOPHER J (US)) 7 February 2002 (2002-02-07)

   D3: US-A-6 103 888 (HIRATA MICHIMASA ET AL) 15 August 2000 (2000-08-15) cited in the application

   D4: SORENSEN OLE ET AL: 'The human antibacterial cathelicidin, hCAP-18, is bound to lipoproteins in plasma' JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 274, no. 32, 6 August 1999 (1999-08-06), pages 22445-22451, XP002257545 ISSN: 0021-9258

2. **Subject-matter of the application**
The present application relates to a peptide defined by SEQ ID NO:6 which encompasses the amino acid residues C108 to R131 of the human full-length FALL-39 preprotein, a member of the human cathelicidin family. After proteolytic cleavage of the preprotein (also known as hCAP-18) the C-terminal region, named FALL-39 peptide, is released which comprises the amino acid positions F132 to S170. The FALL-39 peptide is then further processed to the mature cationic antimicrobial peptide LL-37.

3. **Novelty (Art. 33(2) PCT)**
The present claim 1 is directed to a peptide of 8 to 24 amino acids length of SEQ ID NO:6 having "the biological activity of a Pep714 peptide" which is a fragment of a polypeptide defined by SEQ ID NO:3. Said SEQ ID NO:3 is obtained by proteolytic cleavage of the FALL-39 preprotein (positions C108 to S170 thereof).

Biological activities of a Pep714 peptide are defined on page 12 of the specification (e.g. antimicrobial, antiviral...).

However, either of the documents D1 to D5 discloses an antimicrobially active polypeptide **comprising** the claimed peptide defined by SEQ ID NO:6 and therapeutic uses thereof.

Consequently, the subject-matter of claims 1 to 13 is not novel in the sense of Art. 33(2) PCT.

4. **Inventive step (Art. 33(3) PCT)**
Even if the claims are limited to a peptide **having** the amino acid sequence defined by SEQ ID NO:6 in order to overcome the novelty objections raised above, the subject-matter of the present claims still would lack an inventive step.

In that case the problem to be solved by the present application would be regarded as the provision of "an alternative antimicrobial peptide derived from the hCAP-18 preprotein".

The present application provides a peptide defined by SEQ ID NO:6 in order to solve the problem above.

However, this solution cannot be considered as involving an inventive step (Article

33(3) PCT), since neither any antimicrobial activity of said peptide nor any therapeutic relevance thereof has been disclosed in the application as filed.